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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,537	10/09/2003	Todd Allen Berg	293/034 DIV CON DIV	2610

1473 7590 11/21/2008

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PATENT DOCKETING 39/361
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
11/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/683,537	BERG ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-119,143-145 and 147-150* is/are pending in the application.

4a) Of the above claim(s) *115-119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108-114,143 and 147-150* is/are rejected.

7)☒ Claim(s) *144, 145* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/08 has been entered.

Response to Arguments

Applicant's arguments filed 9/26/08 have been fully considered. For the record, claim 114 is interpreted as positively claiming the device for closing septal defects.

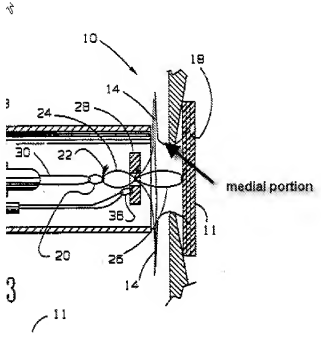
Regarding the by Stevens et al (WO 96/32882) rejection, it is within the scope of the reference that the medial portion and fingers are the same material. Note that the hub 250 and fingers 252 (and includes 260) are stainless steel.

[0015] In a first embodiment, the closure means comprises a patch that may be attached to the cardiac septum to cover and occlude the septal defect. The patch includes a collapsible frame, and a flexible patch material attached to the frame. The flexible patch material may be an artificial biocompatible material such as polyester or expanded polytetrafluorethylene, or a portion of the patient's pericardium or other natural body membrane. The frame is configured to support the patch material at its outer edges in a generally flat configuration, and is sufficiently rigid to retain its shape against the pressure of blood within the heart, while having sufficient flexibility and resiliency to be collapsible for introduction through the inner lumen of the access device. In an exemplary embodiment the frame comprises a hub and a plurality of spokes extending radially outward from the hub. A circumferential wire or suture thread extending between the outer tips of the spokes may be

provided to continuously support the outer edges of the patch. **The hub [element 250] is a rigid material such as stainless** steel, is small enough to fit within the inner lumen of the access device, and is configured to be detachably coupled to the distal end of an delivery shaft (described below). The spokes are flexible, resilient wires of Nitinol.TM. or other material exhibiting similar super-elastic characteristics. The patch may be mounted to the frame by sutures, heat welding, adhesive, or other means.

[0128] FIGS. 24A-24B illustrate still another embodiment of defect repair device 130. In this embodiment, defect repair device 130D has a distal patch 244 of a flexible, biocompatible material attached to a wire frame 246, much like distal patches 206, 208, 210 of FIGS. 21-23. Wire frame 246 may be continuous wire of stainless steel, Nitinol.TM., or other biocompatible, resilient metal or polymer, and may include a plurality of loops 248 like those shown in FIGS. 21-23. Rather than being attached to a proximal patch like the above-described embodiments, however, distal patch 244 of FIG. 24 is attached to a central hub 250, to which are coupled a plurality of radially-extending struts 252 on the proximal side of patch 244 and parallel thereto. While defect repair device 130D is pictured with four such struts in FIGS. 24A-24B, struts 252 may be between three and twelve in number. **Struts 252 are Nitinol, stainless** steel, or other flexible, resilient biocompatible metal or polymer, and are coupled to hub 250 in such a way that the outer ends 254 of struts 252 are biased toward patch 244 and deflectable away from patch 244 about an axis perpendicular to the central axis of hub 250. An additional patch (not shown) may be attached to struts 252 to provide patches on both sides of septum S, although in most cases, a single patch on the higher pressure side of the septum (the left side of the heart) is sufficient to prevent interatrial or interventricular blood flow through a septal defect.

Regarding the Sideris rejection, it is the Examiner position that first and second sets of fingers are unitary with the medial portion as defined above and are formed of the same material. Fingers 18, 14, and the indicated medial portion are all from the same wire material.



Applicant amendment overcame the rejections in view of Lesh et al (6,152,144).

The rejection under 35 U.S.C. 103(a) as being unpatentable over Kazuyuki et al (EP 1013227, applicant cited 11/30/07) in view of Das (5,334,217) has been withdrawn.

Allowable Subject Matter

Claims 144 and 145 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 108-110, 112, 114, 143, 147-150 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stevens et al (WO 96/32882, applicant cited 4/4/08).

Referring to at least figure 25A, Stevens et al teaches:

108. (Currently Amended)

A device for use in closing septal defects comprising: a medial portion including elements 261, 256, 250 (tubular) having a longitudinal axis; and first and second sets of fingers 252, 260 unitary with the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 260 is covered by a web of material 244 between adjacent ones of the fingers.

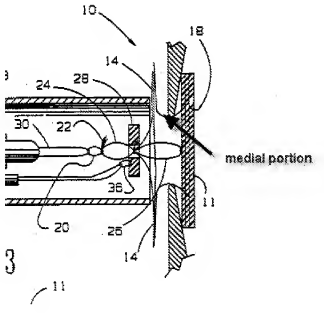
Regarding claim 112, Stevens teaches:

> [0125] Additional embodiments of defect repair device 130 of the invention are illustrated in FIGS. 21A-21B, 22A-22B, 23, and 24A-24B. Defect repair devices 130A, 130B, 130C of FIGS. 21-23 each include a distal patch 206, 208, 210, and a proximal patch 212, 214, 216. The patches are a flexible, biocompatible, and blood impervious material, preferably conducive to endothelialization after implantation. Suitable materials include polyester mesh, knit fabrics of expanded polytetrafluoroethylene treated for low porosity, absorbable polyhydroxybutyrate, autologous pericardium, bovine or porcine pericardium, polyurethane and polypropylene mesh.

Claims 108-110, 112, 114, 143, are rejected under 35 U.S.C. 102(e) as being anticipated by Sideris (5,433,727). Referring to figure 3, Sideris teaches:

108. (Currently Amended)

A device for use in closing septal defects comprising: a medial portion (shown below) having a longitudinal axis; and first and second sets of fingers 18, 14, unitary with the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 18 is covered by a web of material 16 (see figure 1) between adjacent ones of the fingers.



Regarding claim 114, see figure 3. Claim 114 is interpreted as positively claiming the device for closing septal defects.

Regarding claim 143, the device is capable of being formed from a hollow tube as a starting material which is melted down to form wire.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (WO 96/32882).

Stevens teaches the device as described above including the fingers can be made of Nitinol, however, fails to specifically teach the hub in made of Nitinol (such that the medial portion and fingers are formed of the same material). It would have been obvious to one having ordinary skill in the art have tried Nitinol for the rigid hub material for it's well known characteristics such as biocompatibility with predictable results.

Stevens teaches the device as described above, however, fails to specifically teach silicone. It would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility with predictable results.

Claims 111, 113, and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sideris (5,433,727).

Sideris teaches the device as described above, however, fails to specifically teach nitinol. It would have been obvious to one having ordinary skill in the art have used nitinol for such a material for it's well known characteristics such as biocompatibility. Regarding silicone, Sideris teaches polyurethane; it would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility.

Regarding claims 147-150, Sideris teaches an intra-cardiac device made of wire, but fails to teach what material the wire is made of. It would have been obvious to one skilled in the art to have made the wire of Sideris from nickel titanium alloy, stainless steel, thermoplastic, or elastic material for their known use as cardiac device including stents for their known characteristics including biocompatibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce E Snow/
Primary Examiner, Art Unit 3738